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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,944

Applicant(s)

GEORGIADES

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Response to Amendment

1. Claims 1 and 3 have been amended as requested in the amendment of Paper No. 11, filed on December 02, 2002. Claims 1-4 and 7-8 are pending in the instant application.

Claims 1-4 and 7-8 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 102

4. Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 289 278 document for reasons of record in section 6 of Paper No. 10.

Applicant submits that claim 1, as amended, is directed to a dietary supplement comprising purified colostrinin in combination with lactoferrin, and that the reference GB 2 289 278 "clearly does not disclose, teach or suggest a dietary supplement comprising purified colostrinin as claimed" (page 5 of the Response). This argument has been fully considered but is not deemed to be persuasive because the instant specification, as filed, fails to define "purified colostrinin" in such clear terms that one of ordinary skill in the art would be able to distinguish the "purified colostrinin" of the instant invention and colostrinin as recited in GB 2 289 278 document. Therefore, a skilled artisan would readily conclude that purified colostrum, which contains colostrinin, of GB 2 289 278 (see Tables on pages 12-15) meets the limitations of the

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“purified colostrinin” of the instant specification, and, therefore, GB 2 289 278 document anticipates claim 1 of the instant application.

Claim Rejections - 35 USC § 103

5. Claims 2-4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Immuno-Dynamics Inc., 1995 (GB 2 289 278, reference 2 of the IDS of Paper No.6) as applied to claim 1 above, and further in view of Janush et al., 1998, (WO 98/14473, reference 4 of the IDS of Paper No.6), Adler et al. (1997, WO 97/43905, reference 3 of the IDS of Paper No.6), NIKKEN FOOD KK document (1990, JP2265458, reference 5 of the IDS of Paper No.6), and Inglot et al. (1996, Arch. Immunologiae et Terapiae Experimentalis, Vol.44, pp.215-224, reference 6 of the IDS of Paper No.6) for those reasons of record in section 7 of Paper No. 10.

Claims 7-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Immuno-Dynamics Inc., 1995 (GB 2 289 278, reference 1 of the IDS of Paper No.6) as applied to claim 1 above, and further in view of New England Medical Hospitals, Inc. (1997, WO 97/05884, reference 2 of the IDS of Paper No.6), and Adler et al. (1997, WO 97/43905, reference 3 of the IDS of Paper No.6) for reasons of record in section 6 of Paper No. 10.

Applicant traverses the rejections on the premises that the claims, as amended are directed to compositions comprising purified colostrinin and that the recited art does not teach or suggest the use of the purified colostrinin (page 6-7 of the Response). These arguments have been fully considered but are not deemed to be persuasive for the reasons of record as applied to claim 1 earlier in section 4 of the instant office action. Briefly, because the instant specification fails to define the degree of purification of colostrinin to be used in the claimed dietary

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supplement, one skilled in the art would reasonably conclude that purified colostrum of GB 2 289 278 document meets the limitations of "purified colostrinin" of the instant invention.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 7-8, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, as amended, is directed to a dietary supplement comprising purified colostrinin in combination with lactoferrin. Claims 2-4 and 7-8 are depending claims. Applicant submits that the "amendment to claim 1 clearly adds no new matter to the application (support for the amendment to claim 1 can be found on page 4, line 19)", see page 5, second paragraph of the Response. However, the above noted passage of the instant specification, as filed reads as follows: "[t]he colostrinin need not necessarily be in a pure form but may instead be, for example, partially purified as, for example, IgG-colostrinin complex, or in a crude preparation form like whey, so long as the form is physiologically acceptable". Thus, the instant specification, as originally filed, does not provide support for the dietary supplement comprising

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purified colostrinin and, accordingly, the amendment of claim 1 introduced a new matter to the claimed invention.

Conclusion

7. No claim is allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


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Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-7939. Official papers should NOT be faxed to (703) 308-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*


JOHN ULM
PRIMARY EXAMINER
GROUP 1800